

**REMARKS**

Claims 1 to 30 were pending. Without prejudice or disclaimer, Applicants have amended claims 2, 3, 5, 6, 7-10 and 23-24, as set forth in the attached appendix. The amendments are supported by the specification and the originally filed claims. Specifically, claims 7-10 and 23-24 now recite see-through medaka "having in its genome a transgene," which is supported by the term "transgenic" at page 10, lines 7 and 26, and page 30, line 5 of the specification. The Office alleges that a "transgenic" animal has "the transgene incorporated into its genome." Action at page 3. Thus, the term "transgenic" can support the phrase "having in its genome a transgene."

Further, the phrase "wherein said fluorescent protein is expressed specifically in said organ," in newly-amended claims 7-10 and 23-24, finds support in the specification at page 9, lines 15-20, describing "the production of a luminescence in a specific organ [of the see-through medaka of the invention] by introducing a hybrid gene being a fusion of a promoter of a gene that *expresses organ-specifically* and the coding region of the gene encoding a fluorescent protein." (Emphasis added). Similar support is found at page 10, lines 5-11 and 18-24, page 11, lines 22-27, and in Example 3, pages 27-39. Thus, there is no issue of new matter.

Moreover, none of the amendments narrow the scope of the original claims as properly interpreted in light of the specification's disclosures under recent Federal Circuit case law. Indeed, all the amendments involve merely cosmetic changes in phraseology.

With the entry of this amendment, claims 1-30 are now pending.

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**Withdrawal of Claim Rejections under 35 U.S.C. § 112, First Paragraph**

Applicants thank the Office for withdrawing the enablement rejections with respect to claims 1-22 in view of Applicants' arguments. Action at page 2.

**Withdrawal of Claim Rejections under 35 U.S.C. § 102**

The Office withdrew the anticipation rejections of claims 7-22. Action at page 2. The Action states that the rejection is withdrawn "under 35 U.S.C. § 102(b)" in light of "Applicants' amendment of the claims." *Id.* Applicants thank the Office for withdrawing this rejection, but wish to point out that the rejection was made over § 102(a) and that, instead of amending the claims, Applicants argued that "the Tanaka reference is not prior art with respect to the instant application" as the effective filing date of the instant application (June 8, 2000) predates Tanaka's publication date of February 27, 2001. See Applicants' July 15, 2002 Amendment and Response, at page 22.

For at least the above reasons, Applicants request correction of the reason for withdrawing the 35 U.S.C. § 102 rejections of claims 7-22.

**Claim Rejections Under 35 U.S.C. § 112, First Paragraph**

The Office rejected claims 1-30 under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled by the specification. Office Action at page 2. According to the Office, the critical phenotype of the see-through medaka is not included in the claims. *Id.* Applicants submit the following remarks concerning this ground of rejection.

First, Applicants respectfully request reconsideration or clarification with respect to how this rejection applies to claims 1-6. As Applicants understand, the rejection is

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directed to *transgenic* see-through medaka of the invention. Applicants respectfully point out that, unlike the other claims, claims 1-6 do not recite "transgenic see-through medaka." Further, Applicants respectfully point out that claims 1-6 were not amended in the Amendment filed on July 15, 2002, leaving them ineligible for new grounds of rejection allegedly necessitated by Applicants' Amendment. MPEP § 706.07(a).

For at least the above reasons, Applicants earnestly and respectfully request reconsideration and withdrawal of the rejections of claims 1-6 under 35 U.S.C. § 112, first paragraph. In the alternative, Applicants earnestly seek clarification of the rejection with respect to these claims.

Second, with respect to the remaining claims, Applicants wish to thank the Office for its suggestion for overcoming this rejection. Office Action at page 3. The Office suggested amending the claims to recite "a transgenic see-through medaka having in its genome a transgene . . . wherein said fluorescent protein is expressed specifically in said organ." *Id.*

Nonetheless, Applicants reject the Office's characterization of the phenotype of the transgenic see-through medaka as being critical or essential to the practice of the invention. Action at page 2. Applicants further traverse the contention that claims 7-30 allegedly fail to recite the phenotype of expressing fluorescent protein in a specific organ. Action at page 3.

Still, solely to facilitate prosecution, and without acquiescing to the rejection, Applicants have amended claims 7-30. Amended independent claims 7-10 and 23-24 now recite both suggested phrases, "having in its genome a transgene" and "wherein said fluorescent protein is expressed specifically in said organ." Further, claims 11-22

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and 25-30 depend from claims 7-10 and 23-24, and thus are also amended accordingly. That is, claims 11-14 and 15-18 depend directly from claims 7-10; claims 19-22 depend directly from claims 11-14, and thus indirectly from claims 7-10; claims 25-26 and 27-28 depend directly from claims 23-24; and claims 29-30 depend directly from claims 25-26 and thus indirectly from claims 23-24. Finally, as noted above, the amendments are supported by the specification and add no new matter. (See, for example, Specification at page 10, lines 7 and 26, and page 30, line 5; as well as page 9, lines 15-20, page 10, lines 5-11 and 18-24, page 11, lines 22-27, and Example 3, pages 27-39).

In sum, Applicants respectfully submit that the pending claims, as presently amended, are in compliance with 35 U.S.C. § 112, first paragraph. Thus, Applicants earnestly request reconsideration and withdrawal of the enablement rejection.

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## Conclusion

In view of the foregoing remarks, Applicants submit that all of the pending claims, as now amended, are in condition for allowance. Thus, Applicants earnestly and respectfully request timely issuance of a Notice of Allowance.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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## APPENDIX

2. (Amended) The see-through medaka according to claim 1 wherein said medaka is produced by [means of] repeated selective mating between iridophore deficient mutant medaka strain gu, albino mutant medaka strain i-3 and leucophore deficient mutant medaka strain 1f.

3. (Amended) A see-through medaka wherein said medaka is produced by [means of] further selective mating between the see-through medaka according to claim 2 and iridophore deficient mutant medaka strain il-1.

5. (Amended) The see-through medaka according to claim 4 wherein said medaka is produced by [means of] repeated selective mating between iridophore deficient mutant medaka strain gu, albino mutant medaka strain i-3, leucophore deficient mutant medaka strain 1f and medaka FLF strain which is deficient in leucophores in the female.

6. (Twice amended) A see-through medaka wherein said medaka is produced by [means of] further selective mating between the see-through medaka according to claim 3 and a see-through medaka produced by [means of] repeated selective mating between iridophore deficient mutant medaka strain gu, albino mutant medaka strain [I]i-3, leucophore deficient mutant medaka strain 1f, and medaka FLF strain which is deficient in leucophores in the female.

7. (Twice amended) A transgenic see-through medaka deficient in iridophores, melanophores, xanthophores and leucophores, having in its genome a transgene [wherein a specific organ is allowed to produce luminescence by introducing a hybrid gene] being a fusion of a promoter of a gene which expresses specifically in [said]

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a specific organ, with a coding region of a gene encoding a fluorescent protein, wherein said fluorescent protein is expressed specifically in said organ.

8. (Twice amended) A transgenic see-through medaka produced by [means of] further selective mating between the see-through medaka according to claim 2 and iridophore deficient mutant medaka strain il-1, having in its genome a transgene [wherein a specific organ is allowed to produce luminescence by introducing a hybrid gene] being a fusion of a promoter of a gene which expresses specifically in [said] a specific organ, with a coding region of a gene encoding a fluorescent protein, wherein said fluorescent protein is expressed specifically in said organ.

9. (Twice amended) A transgenic see-through medaka deficient in iridophores, melanophores and xanthophores, wherein the sex of said medaka can be identified by the presence or absence of leucophores and/or a DNA marker, having in its genome a transgene [wherein a specific organ is allowed to produce luminescence by introducing a hybrid gene] being a fusion of a promoter of a gene which expresses specifically in [said] a specific organ, with a coding region of a gene encoding a fluorescent protein, wherein said fluorescent protein is expressed specifically in said organ.

10. (Twice amended) A transgenic see-through medaka produced by [means of] further selective mating between the see-through medaka according to claim 3 and a see-through medaka produced by [means of] repeated selective mating between iridophore deficient mutant medaka strain gu, albino mutant medaka strain i-3, leucophore deficient mutant medaka strain 1f, and medaka FLF strain which is deficient in leucophores in the female, having in its genome a transgene [wherein a specific organ is allowed to produce luminescence by introducing a hybrid gene] being a fusion of a

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promoter of a gene which expresses specifically in [said] a specific organ, with a coding region of a gene encoding a fluorescent protein, wherein said fluorescent protein is expressed specifically in said organ.

23. (Amended) A transgenic see-through medaka produced by [means of] repeated selective mating between iridophore deficient mutant medaka strain gu, albino mutant medaka strain i-3 and leucophore deficient mutant medaka strain 1f, having in its genome a transgene [wherein a specific organ is allowed to produce luminescence by introducing a hybrid gene] being a fusion of a promoter of a gene which expresses specifically in [said] a specific organ, with a coding region of a gene encoding a fluorescent protein, wherein said fluorescent protein is expressed specifically in said organ.

24. (Amended) A transgenic see-through medaka produced by [means of] repeated selective mating between iridophore deficient mutant medaka strain gu, albino mutant medaka strain i-3, leucophore deficient mutant medaka strain 1f and medaka FLF strain which is deficient in leucophores in the female, having in its genome a transgene [wherein a specific organ is allowed to produce luminescence by introducing a hybrid gene] being a fusion of a promoter of a gene which expresses specifically in [said] a specific organ, with a coding region of a gene encoding a fluorescent protein, wherein said fluorescent protein is expressed specifically in said organ.

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